

Message

From: Gwinn, Maureen [gwinn.maureen@epa.gov]
Sent: 11/9/2016 9:10:49 PM
To: Bahadori, Tina [Bahadori.Tina@epa.gov]; Kavlock, Robert [Kavlock.Robert@epa.gov]; Cascio, Wayne [Cascio.Wayne@epa.gov]; Thomas, Russell [Thomas.Russell@epa.gov]; Deener, Kathleen [Deener.Kathleen@epa.gov]; Bussard, David [Bussard.David@epa.gov]; Axelrad, Daniel [Axelrad.Daniel@epa.gov]; Dix, David (NIH/NCATS) [V] [david.dix@nih.gov]; Burke, Thomas [Burke.Thomas@epa.gov]
Subject: RE: Reframing Risk paper : Materials for discussion on 11/14
Attachments: Reframing Chemical Risk Assessment-4-5 key messages.docx; Reframing Chemical Risk Assessment-1109v2.docx; Reframing Risk Figures 100216 -dan.pptx

Thanks to all who sent in their 4-5 key messages (compiled and attached). In reviewing these messages, the group as a whole is fairly consistent (a good thing). I have not revised the current draft to reflect these messages yet.

I'm out of town this weekend, but propose that we discuss on Monday tightening the text in the paper to focus in on the key messages, and to clear out any areas that seem to be somewhat distracting from those messages. I will be able to turn around a draft next week following that discussion.

Also, we are looking into AJPH for the home for this article. My hope is to get this sent out to the journal before Thanksgiving.

Thanks all – and have a great weekend.

Maureen

Maureen R. Gwinn, PhD DABT ATS
Science Associate/IOAA

t(202)564-4621
m(703)434-9093

From: Gwinn, Maureen
Sent: Sunday, October 30, 2016 8:35 PM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Kavlock, Robert <Kavlock.Robert@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Thomas, Russell <Thomas.Russell@epa.gov>; Deener, Kathleen <Deener.Kathleen@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Axelrad, Daniel <Axelrad.Daniel@epa.gov>; Dix, David (NIH/NCATS) [V] <david.dix@nih.gov>; Burke, Thomas <Burke.Thomas@epa.gov>
Subject: Reframing Risk paper : 4-5 key messages Due 11/7/16

Hi all –

Following up in Tina and Bob's notes below please send me your 4-5 key messages by 11/7/16. I will compile and share with all to discuss at our scheduled meeting on 11/14/16.

Attached is the current draft with all edits (track) and a clean version for your review. There are one or two comments that I need to get some clarification on before addressing – I will reach out individually to address.

I'm including the figures with Dan's comments still included.

Thank you

Maureen

Maureen R. Gwinn, PhD DABT ATS
Science Associate/IOAA

t(202)564-4621
m(703)434-9093

From: Bahadori, Tina

Sent: Wednesday, October 26, 2016 1:19 PM

To: Kavlock, Robert <Kavlock.Robert@epa.gov>; Gwinn, Maureen <gwinn.maureen@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Thomas, Russell <Thomas.Russell@epa.gov>; Deener, Kathleen <Deener.Kathleen@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Axelrad, Daniel <Axelrad.Daniel@epa.gov>; Dix, David (NIH/NCATS) [V] <david.dix@nih.gov>; Burke, Thomas <Burke.Thomas@epa.gov>

Cc: Laura Romano <lromano@gwmail.gwu.edu>

Subject: RE: Reframing Risk paper revised

Hi Everyone,

I finished reviewing the latest version of the paper. The paper is good, but there are too many key messages, so none emerges with strength....or perhaps they need to be connected better. I think I agree with Bob that we each need to identify the top messages and see if we can distill this further? I also think it might be helpful to have one more meeting to converge on these points. In any case, here are my 'straw' points – I'm laying them out for your (strong) reactions ☺.

Thanks,

Tina

Background:

- In the field of environmental health, risk assessment has evolved more and more to support regulatory decision making.
- But regulations, by nature, are media and source specific. And because they require regulatory actions that impact the regulated community, they demand bright lines and at times definitive proof of causality before action can be taken.
- There is a remarkable history of success. Overt impacts of a number of environmental exposures have been characterized. Many have resulted in regulatory and policy actions of historic proportions – implementation of the NAAQS is an example.
- In the domain of chemical risk assessments, there have been additional challenges in that, with the exception of pesticides, little information is available on the hazards and exposures of the majority of chemicals in commerce.
 - Most of the data that informs risk assessments are derived from standardized animal tests that evaluate chemicals at relatively high levels of exposures, not typically represented in human populations.
- Epi studies show effects where animal studies don't
- This discordance reinforces concerns about the adequacy of contemporary risk assessment practices.
- New opportunity: Science and technology have evolved, and now we have a myriad of new data streams
 - HT testing
 - Molecular epi
 - Exposomic markers
 - Non-targeted analyses – biosamples, env. samples, products
 - Exposure estimations (such as expocast)
 - AOP Networks

In this paper:

-
- **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

From: Kavlock, Robert

Sent: Monday, October 24, 2016 2:57 PM

To: Gwinn, Maureen <gwinn.maureen@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Thomas, Russell <Thomas.Russell@epa.gov>; Deener, Kathleen <Deener.Kathleen@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Axelrad, Daniel <Axelrad.Daniel@epa.gov>; Dix, David (NIH/NCATS) [V] <david.dix@nih.gov>; Burke, Thomas <Burke.Thomas@epa.gov>

Cc: Laura Romano <lromano@gwmail.gwu.edu>

Subject: RE: Reframing Risk paper revised

Some comments from me. I think it would be good for everyone to think about their 4-5 keys messages for this paper (similar to what some of us did on the innovation paper).

Bob

From: Gwinn, Maureen

Sent: Tuesday, October 04, 2016 9:40 PM

To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Kavlock, Robert <Kavlock.Robert@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Thomas, Russell <Thomas.Russell@epa.gov>; Deener, Kathleen <Deener.Kathleen@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Axelrad, Daniel <Axelrad.Daniel@epa.gov>; Dix, David (NIH/NCATS) [V] <david.dix@nih.gov>; Burke, Thomas <Burke.Thomas@epa.gov>

Cc: Laura Romano <lromano@gwmail.gwu.edu>

Subject: Reframing Risk paper revised

Hi all -

Please review the attached draft manuscript on reframing risk. This is largely final, it just needs an abstract and to be formatted this for the Lancet Global Health journal (instructions to authors attached as an FYI). The word count is slightly over the 3,000 word count (not including tables, figures and references) so some further streamlining will be needed, but I wanted to give you all an opportunity to review and suggest final edits. Figures are attached in ppt and pdf for easier viewing on iphones.

Please send any comments back to me by COB 10/17/16, and we will plan to submit to the Lancet soon after.

Thank you!

Maureen

Maureen R. Gwinn, PhD DABT ATS
Immediate Office of the Assistant Administrator
Office of Research and Development
US Environmental Protection Agency

t(202)564-4621
m(703)434-9093